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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,274	02/10/2004	Huiyan Guo	ISA-128.01.	1279
63767	7590	06/27/2007		
FOLEY HOAG, LLP PATENT GROUP (w/ISA) 155 SEAPORT BLVD. BOSTON, MA 02210-2600			EXAMINER NGUYEN, BAO THUY L	
			ART UNIT 1641	PAPER NUMBER
			MAIL DATE 06/27/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/775,274

Applicant(s)

GUO ET AL.

Examiner

Bao-Thuy L. Nguyen

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 13-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. The amendment submitted on 26 April 2007 has been received.
2. Claims 1-12 and 22-35 have been canceled.
3. Claims 13-21 are pending.
4. All rejections not reiterated herein below are withdrawn in view of the amendments to the claims.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claims 13-18 are rejected under 35 U.S.C. 102(b) as being anticipated by May et al (WO 88/08534).

May discloses an assay device comprising a test strip having a control zone and a test zone and means for detecting test results and control results comprising dye loaded liposomes or colloidal gold particles (page 10). The control zone is loaded with an antibody that will bind to a labeled antibody and exhibit a detectable signal. The control zone can contain also an anhydrous reagent that when moistened, produces a color change or color formation. Or as an alternative, the control zone could contain immobilized analyte which will react with excess labeled reagents from the first zone (page 9). Quantitative measurement may be done visually by eye or by instrument (page 10, lines 10-13).

7. Claims 13-21 rejected under 35 U.S.C. 102(e) as being anticipated by Jerome et al (US 2003/0211634).

Jerome discloses a device comprising a flow matrix having at least three zones. A sample receiving zone, a label zone downstream from the sample zone having mobile labeled reagent specific for an analyte of interest, an observation area downstream of the label zone containing immobilized capture reagents specific for the analyte of interest. See paragraphs [0031] and [0032]. Jerome teaches labels comprising colloidal particles, dyed or colored latex particles, etc. See paragraph [0061]. The flow matrix is

disposed on a matrix which bears a detectable mark thereon. The mark is placed directly underneath the observation area is invisible until a liquid sample is added. See paragraph [0035]. The mark is placed in a precisely controlled location within the window and can be printed directly on the plastic housing or on an intermediate member disposed between the housing and the test strip. Jerome also discloses a procedural control line in the observation area. The control line binds a label unrelated to the labeled analyte binding partner. Jerome also teaches an end of assay control zone indicator such a pH indicating reagent impregnated in the absorbent zone or at a location downstream of the capture zone. Upon contact with the sample, a pH change occurs in the processed matrix and is seen in an observation window over the control zone. See paragraphs [0100] and [0101].

### *Response to Arguments*

8. Applicant's arguments filed 26 April 2007 have been fully considered but they are not persuasive.

Applicant argues that May does not teach a device comprising a test strip having a control results zone and a test result zone; an analyte detection means comprising multiple particles and a control detection means comprising at least one detectable dye reagent disposed downstream of the particles.

These arguments are not persuasive. May discloses a device comprising a labeled zone having antibodies bearing a colored direct label configured to bind with

the analyte of interest, a detection zone having an immobilized binding partner for the complex between the labeled reagent and the analyte and a control zone comprising an anhydrous reagent that will produce a color change when moistened by an aqueous sample. See page 7, line 23 through page 9, line 35. Clearly, the colored particle-label reagent of May is disposed as multiple particles and not ONE particle. See page 33, lines 10-28 where May teaches the production of the labeled reagents, and page 36, lines 5-26 where May discloses the deposition of labeled-reagents on a test strip. May also specifically teaches that the signal in the control zone is designed to convey to the use that liquid sample has permeated the test strip. See page 9, lines 22-23.

### *Conclusion*

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

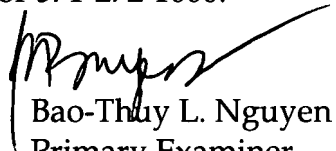
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date

of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday -- Thursday from 9:00 a.m. - 3:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Bao-Thuy L. Nguyen  
Primary Examiner  
Art Unit 1641